



**UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/384,248	02/06/95	ALIZON	M 3495.0008-08

HM11/0303  
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EXAMINER

PARKIN, J

ART UNIT PAPER NUMBER

1648

DATE MAILED: 03/03/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
**08/384,248**

Applicant(s)  
**Alizon et al.**

Examiner  
**Jeffrey S. Parkin, Ph.D.**

Group Art Unit  
**1648**



☒ Responsive to communication(s) filed on 16 Jan 1998

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 23 and 26-33 is/are pending in the application.

Of the above, claim(s) 26-31 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 23, 32, and 33 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Serial No.: 08/384,248  
Applicants: Alizon et al.

Docket No.: 3495.0008-08  
Filing Date: 02/06/95

**Response to Amendment Filed Pursuant  
to 37 C.F.R. § 1.129**

**37 C.F.R. § 1.129(a)**

1. Since this application is eligible for the transitional procedure of 37 C.F.R. § 1.129(a), and the fee set forth in 37 C.F.R. § 1.17(r) has been timely paid, the finality of the previous Office action is hereby withdrawn pursuant to 37 C.F.R. § 1.129(a). Applicants' submission after final filed on 26 November, 1998, has been entered. Claims 23, 32, and 33 are currently pending while claims 26-31 have been withdrawn from further consideration by the examiner, pursuant to 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

**35 U.S.C. § 103(a)**

2. The previous rejection of claims 23, 32, and 33 under 35 U.S.C. § 103(a) as being unpatentable over Hobson et al. (1985) in view of Hurn et al. (1980), is hereby withdrawn.

**35 U.S.C. § 112, First Paragraph**

3. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 23, 32, and 33 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In *re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). In *re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976). The claimed

invention is directed toward methods for the production of antibodies to HIV-1 antigens encoded by three  $\lambda$ -J19 restriction fragments (e.g., KpnI (~6,100)/BglIII (~9,150); KpnI (~3,500)/BglIII (~6,500); and, PstI (~800)/KpnI (3,500)). Presumably these restriction fragments correspond to the gag, pol, and env genes. The disclosure does not provide the nucleotide sequences of any of these restriction fragments, evidence that bona fide viral antigens were produced from said fragments, and evidence that antigen-specific antibodies were produced.

The written description requirement under Section 112, first paragraph, stipulates that the claimed subject matter must be supported by an adequate written description that is sufficient to enable anyone skilled in the art to make and use the invention. The courts have decided that the specification must demonstrate that the inventor had possession of the claimed invention as of the filing date relied upon. Although the claimed subject matter need not be described identically, nonetheless, the disclosure relied upon must convey to those skilled in the art that applicants had invented the subject matter claimed. *Ralston Purina Company v. Far-Mar-Co., Inc.*, 227 U.S.P.Q. 177 (C.A.F.C. 1985). *In re Wilder, et al.*, 222 U.S.P.Q. 369 (C.A.F.C. 1984). *In re Wertheim, et al.*, 191 U.S.P.Q. 90 (C.C.P.A. 1976). *In re Blaser, Germscheid, and Worms*, 194 U.S.P.Q. 122 (C.C.P.A. 1977). *In re Driscoll*, 195 U.S.P.Q. 434 (C.C.P.A. 1977). *Utter v. Hiraga*, 6 U.S.P.Q.2d 1709 (C.A.F.C. 1988).

This rejection is not based upon enablement considerations. The Examiner does not dispute the scientific findings that the skilled artisan, at the time of filing, provided with a restriction fragment capable of encoding a known antigen, could express and purify the antigen of interest and employ this protein to generate antigen-specific antibodies. This rejection is based upon the inability of the disclosure to reasonably convey to the skilled artisan that applicants were in possession of the claimed HIV-1 antigens and

antibodies at the time of the filing date relied upon. The specification fails to provide any demonstrative evidence that applicants had generated expression vectors containing the claimed inserts, transfected suitable hosts, and produced suitable levels of recombinant HIV-1 proteins. Moreover, the disclosure fails to provide any evidence suggesting that these antigens were used to immunize animals and that HIV-1-specific antibodies were actually generated. Applicants may obviate this rejection by providing the appropriate scientific documentation.

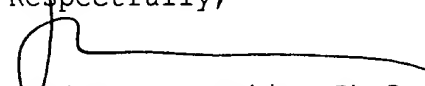
### Correspondence

5. The Art Unit location of your application in the Patent and Trademark Office has changed. To facilitate the correlation of related papers and documents for this application, all future correspondence should be directed to **art unit 1648**.

6. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242 or (703) 305-3014. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 305-7939. Applicants are encouraged to notify the Examiner prior to the submission of such documents to facilitate their expeditious processing and entry.

7. Any inquiry concerning this communication should be directed to **Jeffrey S. Parkin, Ph.D.**, whose telephone number is **(703) 308-2227**. The examiner can normally be reached Monday through Thursday from 8:30 AM to 6:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, **Donald E. Adams, Ph.D.**, can be reached at **(703) 308-0570**. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Respectfully,

  
Jeffrey S. Parkin, Ph.D.  
Patent Examiner

  
**LAURIE SCHEINER**  
**PRIMARY EXAMINER**

Art Unit 1648  
28 February, 1998